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Review - Reconstructive Urology

Genital Reconstructive Surgery in Male to Female Transgender Patients: A Systematic Review of Primary Surgical Techniques, Complication Profiles, and Functional Outcomes from 1950 to Present Day

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Context: Genital reconstructive surgery (GRS) is a necessary part of transitioning for many transwomen, and there is evidence of positive effects on a person's well-being and sexual function. Surgical techniques have evolved, from pursuing aesthetic outcome to now functional outcome with natal females as the standard.

Objective: To systematically review the evidence, identifying the surgical techniques used in primary GRS, their complications, functional outcomes, and the tools used to assess them. Evidence acquisition: The clinical question was designed using the standard PICOS format. The search complied with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2009 statement and was performed by two independent reviewers. Evidence synthesis: Europe, USA, and Thailand favour the penoscrotal technique for vaginoplasty, whereas in the UK, the penile inversion (PI) technique predominates. Primary vaginoplasty using a segment of bowel is less common, and all three techniques have comparable rates of intraoperative rectal injury. The incidence of rectovaginal fistula is reportedly higher in the PI technique. Wound haematoma and vaginal prolapse rates are comparable. Higher rates of clitoral necrosis, urethral meatal stenosis, and wound infection are reported in Pl. However, the ability to orgasm, ability to have penetrative sexual intercourse, and satisfaction with aesthetic result are better with Pl. Conclusions: The evidence for GRS complications and functional outcomes is of low level. Standardised nomenclature reporting of adverse events and robust patient-reported outcome measures (PROMs) are lacking. PROMs are a powerful assessment tool, and standardised definitions of adverse events and functional outcomes should be a priority of future research. Patient summary: We looked at all studies published on genital reconstructive surgery from 1950 to the present day. We assessed each surgical technique and their associated complication rates, sexual and urinary function outcomes, and how they were reported. We found the evidence to be low and weak. We suggest more robust ways of reporting complications, and the impact on patients' quality of life should be investigated.

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1. Introduction

The epidemiology of gender dysphoria has been reported variably (see Table 1) [1-7]. A systematic review in 2015 looked at the prevalence and incidence of gender dysphoria, and the authors included 21 appropriate studies (1974-2014), 12 of which had sufficient data for metaanalysis [4]. They reported the overall prevalence of transwomen to be 1 in 11 650 (8.6 per 100 000) [4]. However, all data published were heterogeneous in the way transgender people were identified and were limited to those who presented to gender identity clinics with gender dysphoria. had commenced hormone therapy, or had undertaken genital reconstructive surgery. However, there are no published data regarding gender variance or gender nonconforming identity, and the considerable social, personal, and financial barriers faced, along with limitations in access to services in some regions, have resulted in a feeling that this is an underestimate of prevalence [4].

Transsexual people may choose to align their outward appearance and role in society with that of their perceived gender. In the case of male to female transsexual patients, the transwoman will live and work as a woman. She may elect to make alterations to her outward appearance, and permanent changes require hormonal manipulation and surgical correction. Not all transwomen choose to undergo genital reconstructive surgery, but for many it is a necessary step in their life journey marrying their bodies with their perceived gender. There is evidence to support genital reconstructive surgery and its positive effects on a person's well-being and sexual function [2,8-14]. In the UK, the National Health Service (NHS) commissions genital reconstructive surgery recognising that surgery can help those people become functioning and contributing members of the society rather than being marginalised outsiders.

In this review, we have looked at 67 yr of literature. Gender dysphoria was first described in 1949 by Caudwell and again by Benjamin in 1953 as psychopathia transsexualis, and the first paper on transsexualism was subsequently published in a psychotherapy journal in 1954 [7]. The first recorded genital surgery for gender dysphoria was performed in Europe in the early 1900s [7]. The very first case was a transman in 1917, but perhaps the most famous one is well chronicled in the book "Man into woman" written by the transwoman herself, Lile Elbe, in 1930 (and most recently made into Hollywood blockbuster *The Danish Girl*). Genital reconstructive surgery was first performed in the USA in 1966 at the John Hopkins Medical Centre, and it is from around this time that more

comprehensive medical literature appears [7]. The authors have looked at studies (of six or more patients) rather than case reports in this systematic review and, as a result, have therefore elected to analyse the medical literature from 1950 to present day. The fundamental principles of genital reconstruction at earlier time were similar to those of modern day surgery, although more often performed as staged operations: orchidectomy, penectomy, and then vaginoplasty.

What is striking is the progress that the medical fraternity has made in how it identifies with transgender people. Early papers would refer to male to female transsexual patients using male pronouns or as male transsexuals. Today, we describe the transwoman in medical literature recognising her female identity. Similarly, genital reconstructive surgery, as it is now known, has been referred to in many different ways over the years: transsexual surgery, sex reassignment surgery, gender reassignment surgery, gender confirming surgery, and gender affirming surgery. Follow-up studies and outcome measure definitions have also changed. In early studies, integration into society and "stability" were major outcome measures, defined by whether the patient had married without their spouse knowing their natal sex phenotype. The purpose of original male to female transsexual surgery was often simply to remove the unwanted male genitalia. As techniques developed, a more feminine perineum was achieved. It is the transwoman who has then driven further changes in technique, and unlike any other field of surgery, these women have pushed surgeons to focus on functional as well as aesthetic results. How we measure these outcomes has also begun to shift from surgeon reported to patient reported, and where emphasis might have previously been more on aesthetic outcomes, it is now just as important to the patient to have good functional outcomes assuming a great aesthetic comparable with natal female genitalia.

The principles of male to female genital reconstructive surgery are to reconstruct appearance and function taking natal females as the standard. The neovagina must be hairless, moist, and have elastic epithelium with minimum dimensions of 11 cm depth and 3 cm width [11,13]. Labia minora, majora, and a sensate clitoris must also be present [11,13,14]. It was common in the early 2000s to do this in a two-staged procedure, where patients underwent a separate labiaplasty 8–12 wk after initial operation, with a Z-plasty on the reconstructed mons pubis to pull the labia majora together, thus creating labia minora. All these are now more usually performed in one stage at the initial operation.

Table 1 - Summary of transgender epidemiology currently reported in the literature.

	UK	Europe	North America
Gender dysphoria (presentation to Gender Identity Clinic)	1 in 5000	0.44-12.11 in 100 000	No published data
Genital reconstructive surgery (includes both MTF and FTM genital surgery)	No published data	4.03-11.57 in 100 000	No published data
Prevalence of "transsexualism"	No published data	1 in 12 900	1 in 100 000

The variations in technique come from which tissue is used to construct the neovagina. The "penile inversion technique" involves degloving the penis via a midline perineal incision, closing the end of the skin tube and invaginating that into the newly dissected neovaginal cavity. An incision is made on the superior aspect of the invaginated skin tube to expose the neoclitoris and to allow subsequent urethral meatoplasty. The "penoscrotal technique" involves creation of a flap of scrotal skin, raised on the posterior scrotal arteries and anastomosed to the penile skin tube, which is opened in the midline ventral aspect to provide adequate width and depth. Where adequate neovaginal depth cannot be achieved with penile inversion or penoscrotal techniques, a bowel substitution vaginoplasty involves anastomosing a segment of bowel (ileum, sigmoid, and colon have been used) brought down on its mesentery to the perineal skin directly, if primary surgery, or cuff of inverted skin when skin techniques have failed (Fig. 1).

Worldwide penoscrotal techniques seem to predominate with some using free skin grafts to add depth. The UK seems to use the penile inversion technique more [15]. A variant on this technique is using the redundant urethra after it has been shortened for meatoplasty as a pedicled flap to line the anterior neovaginal wall. In more recent years, transgender patients are commencing hormone therapy in early adolescence with a resulting penile hypoplasia that can make creating a neovagina with adequate depth impossible. While studies have described using segments of bowel in revision surgery to create an adequate neovagina, more recently surgeons are describing using bowel for the neovagina in primary genital reconstructive surgery, with many using a laparoscopic approach to harvest the bowel [16,17].

The objective of this systematic review was to evaluate the various surgical techniques for primary genital reconstructive surgery in transwomen from 1950 to the present day. We set out to report a literature consensus on the complication profile expected with each surgical technique, and to evaluate and report on a literature consensus for functional outcomes. We are looking to ascertain how

functional outcomes are defined by the surgeon and by the patient, as well as providing comment on the literatures' level of evidence and how confident we can be in any recommendations made.

To achieve the above objectives, we aim to systematically identify papers using relevant search terms and select appropriate original studies for inclusion. Each paper is then to be critiqued, and data are to be extracted and synthesised to relevant summaries of evidence. We aim to identify what techniques are used, what their individual complication profiles are, and what functional outcomes are recorded.

2. Evidence acquisition

A literature search was systematically performed by two independent researchers. Search terms included genital reconstructive surgery, transgender surgery, gender reassignment surgery, sex reassignment surgery, transsexual surgery, complications, adverse events, functional outcomes, and patient-reported functional outcomes (see the Supplementary material for a complete list of search terms). Studies with no English translation available and case reports (fewer than six patients) were excluded. Studies were reviewed from 1950 to the present day. A total of 1292 studies were identified on initial search of PubMed, Medline, CENTRAL, Ovid, and EMBASE databases. Unpublished work was not included in this search. Data acquisition was based solely on search terms and papers identified here. We did not review article references for further studies not identified by our search terms. After abstract screening, 40 studies where identified for full paper review.

Only studies with original data, regarding primary genital reconstructive operations in male to female transgender patients, were included. All review articles with no original data were excluded. Studies that did not identify their technique, studies that looked at more than one technique but did not separate out the data, studies that looked at both primary and secondary bowel neovaginas but did not separate out the data, and studies

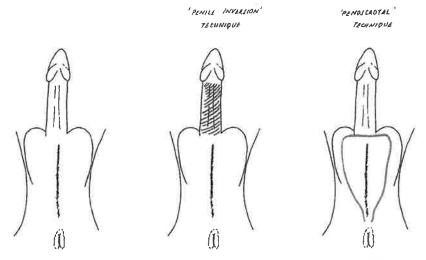


Fig. 1 - Diagramatic representation of the difference in the initial incision for penile inversion versus the penoscrotal technique.

that looked at primary bowel neovaginas in natal females and transgender women but did not separate out the data were excluded.

All included papers were graded according to the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) system of evaluating evidence. Each paper was classified according to its level of evidence (low, moderate, or high) and then according to its strength of evidence, or our confidence in that evidence (weak or strong). This surgery is not performed in very large numbers, and as such all papers were cohort studies, most of which were retrospective analyses of a single surgeon's or a group of surgeons' work over several years. By definition, these are all judged as low-level evidence. Even the larger series, when compared with other surgical fields, are very small. However, when referenced in the context of the size of the transgender community, there are some large series that were judged to be a moderate strength of evidence within their field. The confidence in the data was variable. When judging the strength of the recommendation from each paper, these large studies with clearly defined complications were graded as strong. Where papers had poorly defined complication reporting or were using questionnaires not validated in the transgender patient or any patient group (study author constructed), the strength of the recommendation from each paper was judged to be weak. Unfortunately, most of the evidence in this field of surgery is of low level and weak in its recommendation.

Data extraction was performed by two independent researchers and cross-referenced for errors.

Statistical analysis was not possible, as the data extracted for complications and functional outcomes were very heterogeneous. This is a result of nomenclature changing over the years, as well as English translations not always being colloquial to

English-speaking surgeons, such that complications are described in a number of different ways. Functional outcomes are also often not well defined, and usually the construct of a questionnaire was designed and worded by the study author. Some functional outcomes are reported purely by the study author, while others are patient reported. For example, regarding the reporting of sexual function, patients are asked to comment in author-designed questionnaires on whether they have "erogenous sensibility of the neoclitoris" in one paper [11] and whether they are "able to achieve orgasm" in another [18]. Other papers have simply asked for satisfaction during intercourse regarding vaginal function and clitoral sensation using a subjective Likert scale [1]. These are all very different functional outcomes to describe, and in the absence of a standardised way of asking the question, validated in this patient group, the answers will be difficult to interpret.

Reporting of complications suffers similar heterogeneity. Without standard complication reporting systems in place, studies were not declaring the absence of certain significant complications such as development of rectovaginal fistula, which is a rare but recognised complication of this surgery. Ambiguity in reporting of postoperative bleeding versus haematoma formation, and whether that required return to theatre or alternatively blood transfusions are other examples [19,20].

The lack of standardised outcome measures for both complications and functional outcomes made it impossible to perform a statistical analysis that one could be confident in reporting. As such, all the data are summarised for each technique and reported as percentage ranges.

3. Evidence synthesis

During the perioperative period, the key differences noted are the higher rates of bleeding requiring transfusion in the

Table 2 - GRS surgical technique and associated complication profiles.

Complication		Penile inversion technique complication rate, % (no. of occurrences/no. of procedures)	Penoscrotal technique complication rate, % (no. of occurrences/no. of procedures)	Bowel technique complication rate (no. of occurrences/no. of procedures)
Intraoperative	Rectal perforation	2.46 (27/1097)	2.72 (19/699)	2,38 (1/42)
	Bleeding	5.01 (45/899)	3.02 (25/829)	4.76 (2/42)
	Bleeding requiring transfusion	4.07 (30/737)	2,52 (19/753)	=/
Immediate	Wound dehiscence	6.67 (4/60)	11.33 (34/300)	Section of the sectio
	Haematoma	4.26 (19/446)	4.49 (12/267)	_
	Vaginal segment necrosis	2.71 (12/477)	1.6 (21/1312)	2.38 (1/42)
	Abscess	2.71 (20/737)	0 (0/70)	4,76 (2/42)
	Minor wound healing disorders	War and the state of the same	15.38 (12/78)	A STATE OF THE STA
	Urethral necrosis	1.26 (5/398)	-	-
	Wound infection	14,65 (136/928)	4.63 (46/993)	
	UTI	5.14 (22/428)	12.06 (17/141)	-
	Clitoral necrosis	2.75 (19/690)	0.60 (6/993)	THE RESERVE OF THE PARTY OF THE PARTY.
Late	Urethrovaginal fistula	2.46 (21/853)	0.48 (3/626)	0.00 (0/42)
	Rectovaginal fistula	1.49 (15/1004)	0.34 (3/886)	0.00 (0/42)
	Introitus stricture	14.26 (123/862)	2.07 (2/145)	2.38 (1/42)
	Vaginal stenosis	7.19 (98/1363)	9.60 (63/656)	Service of the servic
	Vaginal prolapse	2.84 (35/1233)	2.68 (34/1267)	2.38 (1/42)
	Urethral meatus stenosis	16.25 (200/1231)	10.69 (96/898)	WALLES OF STREET WAY IN
	Urethral prolapse	2.25 (2/89)	#	-
	Aesthetic revisions/revisions to external genitalia required	23.03 (181/786)	21.90 (168/767)	

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Functional outcomes	Penile Inversion technique outcome rate, % (no. of patients reporting the outcome/no. of patients questioned)	Penoscrotal technique outcome tate, % (no. of patients reporting the outcome/no. of patients questioned)	Bowel technique outcome rate, % (no. of patients reporting the outcome/no. of patients questioned)
Ability to orgasm	81.47 (431/529)	68.45 (141/206)	84.00 (21/25)
Erogenous sensibility present	89.19 (165/185)	86.80 (539/621)	
Ability to have penetrative intercourse	61.58 (125/203)	33.33 (3/9)	2 ** :
Satisfactory aesthetic result	85.33 (314/368)	67.86 (19/28)	
Paina	7.50 (43/573)	18.67 (14/75)	2

GRS = genital reconstructive surgery; - = not reported.

Table 4 - Summary of GRADE classification of all papers included in this systematic review.

	Classification of evidence: low Strength of recommendations made: weak	Classification of evidence: low Strength of recommendations made: strong	Classification of evidence: moderate Strength of recommendations made: strong
Number of papers/total number of papers	32/40	7/40	1/40
References as cited in this review paper	[1,2,11,13,14,16,18,19,23-30,32-47]	[12,15,17,20-22,48]	[49]

penile inversion group, higher rates of urinary tract infection in the penoscrotal group, and higher rates of abscess formation in the bowel vaginoplasty group (Table 2). All reported similar intraoperative rectal injury rates; however, long-term, higher rates of rectovaginal fistula formation are reported in the penile inversion group. The reasons for this are unclear and in direct contradiction to this senior author's experience. Higher rates of urethral and introital stenosis are reported in the penile inversion group also. All groups reported similar rates of neovaginal prolapse and minor aesthetic revision. Again, this is in direct contradiction to this senior author's experience, and it would be expected that the "penoscrotal technique" would have a higher incidence of neovaginal skin tube prolapse due to the skin being thicker when compared with the "penile inversion technique".

Ability to orgasm was reported to be lower in the penoscrotal group; however, similar levels of erogenous sensibility were reported in all groups. Patients reported being happier with the aesthetic outcome of penile inversion technique, and more were able to have penetrative intercourse without pain (Table 3). These results should be interpreted with caution; however, as again without validated questionnaires, these questions are open to bias in a patient group, in which not all are sexually active or engaging in penetrative intercourse.

Having a complication is not always associated with less sensation to the neoclitoris or less ability to reach orgasm. Circumcised patients might have altered clitoral sensation, which puts forward the question of whether circumcised patients can expect differing clitoral sensation outcomes [19]. This has not been answered in the literature and might be something for future studies to address, as it will help

with appropriate counselling of patients and managing expectations in the future.

5

Overall regret after surgery is 0–5.5%. "Some regret", although not further defined, is expressed in 5.5% patients, as reported in the literature. "Consistent" regret after surgery is reported at 0.6% [21–23].

4. Conclusions

There are limitations to the literature available in this field of surgery. As a result of the rare prevalence of gender dysphoric patients seeking genital reconstruction, not many surgeons actually perform these operations, and historically they have come from varied disciplines of training. As a result, approaches and innovations in surgical technique have been surgeon specific rather than standardised. Similarly, the reporting of outcomes has not been standardised, and this has been complicated further by the changing nomenclature over the last 67 yr.

For example, how we define "functional outcomes" has changed over the decades. In the 1960s, 1970s and early 1980s, emphasis was on economic stability, social standing, and reintegration into the society, as defined by whether the patient was married, in a heterosexual relationship, or even with a family. Whether the spouse was aware that their partner was a transwoman was also commented on, and this was how functional success was defined [24,25]. For the last 17 yr, emphasis has shifted to define "functional outcomes" more literally. Can the patient have penetrative intercourse? Can the patient achieve orgasm? Is the patient satisfied with the aesthetic appearance? This is often concurrently graded by the surgeon themselves, who rate the cosmetic appearance and neovaginal depth that they may

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^{*} Dyspareunia, dysuria, and chronic and intermittent pain of genital region.

be able to measure. Various tools have been used to formally assess patient satisfaction, including the Female Sexual Function Index, Female Genital Self-Imaging Scale, and the Amsterdam Hyperactive Pelvic Floor Scale—Women. Some authors choose to construct their own questionnaires regarding sexual function, ability to have penetrative sex, and orgasm. Asking a patient whether they are able to have "normal intercourse" however is open to interpretation, and ambiguity does not confer confidence in the data reported. These questionnaires, whether author constructed or preconfigured, are not validated in the transgender group. It continues to make it difficult to draw any meaningful conclusions, especially when a proportion of patients completing these functional questionnaires may not be sexually active at the time of completing them.

Outcomes are largely not formally defined in studies from the methodology. When results are displayed, they are not always tabulated even, but rather discussed in prose, if at all [26,27]. Some studies do not report important negative value outcomes, such as rectoneovaginal fistula rates or patient regret [28]. Secondary corrective surgery is also not always commented on in all studies, but is likely to be of interest to the new patient contemplating surgery. Secondary corrective surgery rates can be higher than one in five patients [20]. The observation of complications in the literature has, therefore, not been very robust.

The key differences that are reported between the three different techniques are in the penile inversion group, which report higher rates of rectovaginal fistula, and urethral and introital stenosis. The ability to orgasm is reportedly lower in the penoscrotal group, despite similar levels of erogenous sensibility. The cause for these discrepancies is unclear and contrary to the senior author's clinical experience. The heterogeneity of these reported results should be interpreted with caution, and as mentioned, many studies did not report negative outcomes. In the absence of standardised reporting, not all outcomes and complications are being accurately reported, or perhaps even reported at all.

The studies are retrospective cohort studies of small sample size by overall literature standards. Taking into account the rare prevalence of gender dysphoric patients seeking genital reconstruction, some cohorts are actually not that small; however, by GRADE standards, the level of evidence remains low, although in some series we can be more confident of the results where larger cohorts are reported (Table 4). Despite this, small numbers in each study make it impossible to perform statistical analysis, and the selection bias of all retrospective studies, particularly in the transgender population, is enormous. Many patients simply do not want to pay the costs of attending outpatient follow-up if there simply is no perceived complication [29], some patients decline to be involved in follow up studies wishing to forget their past, and some become completely uncontactable postoperatively [16]. Some authors further confounded this by simply excluding any patient not sexually active from their functional assessments [16].

The heterogeneity of this patient group itself can be problematic when reporting in the literature. For example, increasing body mass index is becoming problematic across all medical specialities. Many studies have reported on patient mean body mass index of approximately 22–24 kg/m² [13,17,23,29,30]. In the UK, a maximum body mass index of 31 kg/m² is acceptable prior to surgery. Vaginoplasty in more overweight patients will most likely increase the rate of neovaginal prolapse than is currently reported in the literature. Similarly, the average age of the transwoman requesting genital reconstruction is falling. One study postulated that sexual inexperience in the younger transwoman might also confound patient-reported functional outcomes compared with earlier data reported by the more mature transwoman [16].

What is clear from this systematic review of the literature over the last 67 yr is that the literature is deficient in its definition of outcomes of genital reconstructive surgery for the transwoman. Where studies have struggled in the past is in delivering robust patient-reported outcomes. For example, asking whether a patient is "capable of normal intercourse" is fraught with problems. Firstly, "normal intercourse" is not defined here and it is therefore open to interpretation, which confers ambiguous results. Secondly, what does capable mean? Is it as defined by the surgeon who has apparently measured an adequate neovagina, or is it defined by the patient who can use the neovagina for penetrative intercourse without pain or difficulty? The patient-reported outcome measure (PROM) is a far more powerful assessment tool, and standardised definitions of adverse events and functional outcomes should be a priority of future research [31].

The senior author's Team have constructed a PROM to assess functional results from genital reconstructive surgery in transfeminine people. The self-administered questionnaire includes four specific constructs, urinary function, sexual function, cosmetic appearance, and general health and well-being as perceived by the patient, and can be used pre- and postoperatively to assess changes related to surgery. In the postoperative instrument, questions regarding neovaginal dilation and maintenance have been included, a measure of perceived benefit of treatment and the opportunity to report any adverse outcomes of the surgery (complications, readmission, further surgery, etc.). The questions were adapted from existing PROMs following consultation with a patient focus group. The PROMs are in use in centres across the UK, and validation of these PROMs in the transgender population is underway.

The transwoman has been driving forward innovation in surgical technique, first requesting aesthetics and then function to equal that of the natal woman. The transwoman should therefore be at the heart of this future research, and PROMs are integral to standardising genital reconstruction surgery.

Author contributions: Charlotte Dunford had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Dunford, Bell, Rashid. Acquisition of data: Dunford, Bell.

Analysis and interpretation of data: Dunford, Bell. Drafting of the manuscript: Dunford, Bell, Rashid.

Critical revision of the manuscript for important intellectual content: Dun-

ford, Rashid.

Statistical analysis: Dunford, Bell. Obtaining funding: None.

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Appendix A. Supplementary data

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